APR 01 2003

k030390

## 3.0 510(k) Summary



**Sponsor:**

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Bonnie Smith

**Device Name:** Synthes Large Combination Clamp and Dynamization Clip – MR Safe

**Classification:** Class II, 21 CFR 888.3030: "Single/multiple component bone fixation appliances and accessories."

**Predicate Device:** Synthes Combination Clamp and Dynamization Clip

**Device Description:** Synthes Large Combination Clamp and Dynamization Clip-MR Safe are components of an external fixation frame that forms a construct intended to treat long bone and pelvic fractures. The Dynamization Clip is an accessory to the clamp that allows dynamization during bone healing. These devices are intended for use in the MR environment. Frame components accept Synthes Ø11.0 mm carbon fiber rods and Synthes Schanz screws in diameters of 4 – 6 mm.

**Intended Use:** Synthes Combination Clamp and Dynamization Clip – MR Safe are generally intended to be used in the construction of an external fixation frame to treat long bone and pelvic fractures. Specifically, the Synthes Combination Clamp with Dynamization Clip is intended for:

- Stabilization of soft tissue injuries and open or closed fractures;
- Polytrauma;
- Vertically stable pelvic fractures of as a treatment adjunct for vertically unstable pelvic fractures;
- Arthrodesis and osteotomies with soft tissue problems;
- Failures of total joints;
- Neutralization of fractures stabilized with limited internal fixation;
- Non-unions/septic non-unions;
  Intraoperative reduction/stabilization tool to assist with indirect reduction;
- Unilateral rectilinear bone segment transport or leg lengthening.

**Materials:** Clamps – Stainless steel, titanium alloy and cobalt alloy
Dynamization Clip – Cobalt alloy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 01 2003

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301

Re: K030390
Trade/Device Name: Synthes Large Combination Clamp and Dynamization Clip – MR Safe
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: February 4, 2003
Received: February 5, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

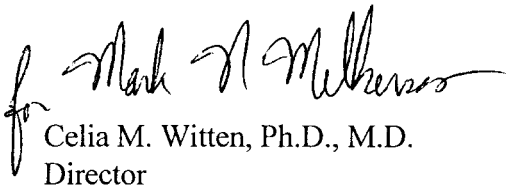
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 2.0 Indications for Use Statement



510(k) Number (if known): K030390

Device Name: Synthes (USA) Synthes Large Combination Clamp and Dynamization Clip – MR Safe

INDICATIONS:

Synthes Combination Clamp and Dynamization Clip – MR Safe are generally intended to be used in the construction of an external fixation frame to treat long bone and pelvic fractures. Specifically, the Synthes Combination Clamp with Dynamization Clip is intended for:

- Stabilization of soft tissue injuries and open or closed fractures;
- Polytrauma;
- Vertically stable pelvic fractures as a treatment adjunct for vertically unstable pelvic fractures;
- Arthrodesis and osteotomies with soft tissue problems;
- Failures of total joints;
- Neutralization of fractures stabilized with limited internal fixation;
- Non-unions;
- Intraoperative reduction/stabilization tool to assist with indirect reduction;
- Unilateral rectilinear bone segment transport or leg lengthening.

for Mark N Milleman
(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K030390

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)